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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,302	09/22/2005	Michihiro Ohnishi	09947.0002-00000	1171

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EXAMINER
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FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

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07/31/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/550,302	<b>Applicant(s)</b> OHNISHI ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 1 April 2008 in which claims 1-13 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 4 January 2008 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a), not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-13 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Quate et al (U.S. Patent No. 7,294,503, published 15 May 2002).

Regarding Claim 1, Quate et al disclose a microchip having a microchannel formed by grooved connecting surfaces of a first upper substrate and a second lower substrate, wherein the microchannel is provided with a gap in which a section of the channel is variable size supplied by a movable protruding part i.e. cantilever (Example 3-4, Column 30-32 and Fig. 3).

Regarding Claim 6, Quate et al disclose a microchip wherein the size of the microchannel is constricted for concentrating and/or analysis of the bead (Fig. 6 & 16, Column 7, lines 14-16, 56-57 and Column 17, line 15-Column 18, line 40).

Regarding Claim 7, Quate et al disclose the microchip wherein the inner surface of the microchannel is treated (Column 19, line 9-41).

### **Response to Arguments**

4. Applicant asserts that Quate et al do not teach the gap having a sectional size variable by a movable protruding part as newly claimed. The assertion is noted but is not found persuasive because as cited above, Quate specifically teaches a cantilever that protrudes into the channel to vary the size of the constriction within the channel. This cantilever of Quate is encompassed by the claimed protruding part, because it is movable and changes the size of the channel when it moves, thus meeting the requirements of the claim.

5. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, filed 22 July 2002).

Regarding Claim 1, Zenhausern et al disclose a microchip having a microchannel formed by grooved connecting surfaces of a first upper substrate and a second lower substrate (§ 48), wherein the microchannel is provided with a gap having a sectional size variable by a movable protruding part i.e. movable array of constrictions (§ 61, 252).

Regarding Claim 2, Zenhausern et al disclose the microchip wherein the gap is formed by protruding parts i.e. first and second protruding parts formed by floating electrode-constriction (#430, Fig. 2 and § 252).

Regarding Claim 3, Zenhausern et al disclose the microchip wherein the gap is formed by opposed protruding parts (Fig. 2, § 252).

Regarding Claim 4, Zenhausern et al disclose the microchip wherein the channel has protruding parts within the channels (Fig. 1 and 2) wherein the constriction inserts the protruding parts of the channels into the grooved channel of the opposing substrate, which are formed by bonding upper and lower substrate (§ 48 and § 60). Hence, the protrusion formed in one substrate is within the channel structure of the other substrate.

Regarding Claim 5, Zenhausern et al disclose the microchip wherein the movable protruding part is either the first or second protruding part (Fig. 2, § 252).

Regarding Claim 6, Zenhausern et al disclose a microchip wherein the microchannel is constricted for concentrating and/or capturing the sample at the constriction wherein the sample is immobilized on a bead (§§ 108, §§ 270-271, Fig. 2).

Regarding Claim 7, Zenhausern et al disclose the microchip wherein the inner surface of the microchannel is treated with biocompatible materials to prevent non-specific binding (§§ 49-50).

### **Response to Arguments**

6. Applicant asserts that Zenhausern et al do not teach the gap having a sectional size variable by a movable protruding part as newly claimed. The assertion is noted but is not found persuasive because as cited above, Zenhausern et al specifically teach a movable array of constrictions within the microchannel (§§ 61) and the reference further illustrates movable constrictions at Fig. 2. The illustrated constrictions protrude into the channel to vary the size of the constriction within the channel. This movable constrictions of Zenhausern are encompassed by the claimed protruding part, because it is movable and changes the size of the channel when it moves, thus meeting the requirements of the claim.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, filed 22 July 2002) in view of Lough et al (U.S. Patent No. 5,900,481, issued 4 May 1999).

Regarding Claims 8-12, Zenhausern et al disclose a microchip having a microchannel formed by grooved connecting surfaces of a first upper substrate and a second lower substrate (§ 48), wherein the microchannel is provided with a gap having a sectional size variable by a movable protruding part i.e. movable array of constrictions (§ 61, 252). Zenhausern et al teach the method of extracting nucleic acids wherein the nucleic acid is absorbed onto the surface as required by Claim 12 (§ 108)

Zenhausern et al further teach the channels are constricted to capture nucleic acid-immobilized on beads for analysis wherein the channel diameter is less than 10µm (§ 47, 252) but they do not specifically teach the bead diameter or hydroxyl functional groups for nucleic acid attachment. However, silica particles of less than 10µm having hydroxyl functional groups were well known and routinely practiced in the art at the time the claimed invention was made as taught by Lough et al.

Lough et al teach silica microbeads having a preferred size of less than 10µm (Column 3, lines 13-15, 25-26) and hydroxyl functional groups (Fig.2) wherein the surface is treated with a silane coupling agent (Fig. 2, Columns 3-4) whereby the nucleic acids for detecting are absorbed onto the surface of the beads (Abstract). Lough et al further teach the functionalization of the beads and surfaces provides differential immobilization chemistry between the bead-surface-nucleic acids (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the bead and surface functionality of Lough et al to the particles of Zenhausern. One of ordinary skill in the art would have been motivated to do so based on the preferred differential immobilization of Lough (Abstract).

9. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, filed 22 July 2002) in view of Smith et al (U.S. Patent No. 6,270,970, issued 7 August 2001) and Lough et al (U.S. Patent No. 5,900,481, issued 4 May 1999).

Regarding Claims 8-13, Zenhausern et al disclose a microchip having a microchannel formed by grooved connecting surfaces of a first upper substrate and a second lower substrate (§ 48), wherein the microchannel is provided with a gap having a sectional size variable by a movable protruding part i.e. movable array of constrictions (§ 61, 252). Zenhausern et al teach the method of extracting nucleic acids wherein the nucleic acid is absorbed onto the surface as required by Claim 12 (§ 108)

Zenhausern et al further teach the channels are constricted to capture nucleic acid-immobilized on beads for analysis wherein the channel diameter is less than 10µm (§ 47, 252) but they do not specifically teach the bead diameter or hydroxyl functional groups for nucleic acid attachment. However, silica particles of less than 10µm having



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hydroxyl functional groups were well known and routinely practiced in the art at the time the claimed invention was made as taught by Lough et al.

Smith et al teach silica microbeads having a preferred size of less than 10 $\mu$ m (Column 12, lines 16-32) and immobilization-specific functional groups (Column 14, lines 45-56) wherein the surface is treated with a silane coupling agent (Column 14, line 57-Column 15, line 12) whereby the nucleic acids for detecting are selectively absorbed onto and released from the surface of the beads based on the presence and/or concentration of chaotropic salts (Column 16, line 58-Column 17, line 25) whereby the salts provide the nucleic acids in an unfolded state (Column 10, lines 43-57).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chaotropic salts of Smith et al to the hybridization methods of Zenhausern and Lough. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing unfolded nucleic acids that are more thermodynamically stable than folded nucleic acids to thereby favor hybrid formation (Smith et al, Column 10, lines 43-57).

#### Response to Arguments

10. Applicant reiterates the arguments regarding protruding parts and the teachings of Zenhausern. Applicant asserts that Lough and/or Smith do not cure the deficiencies of Zenhausern. The arguments have been considered but are not found persuasive because, as stated above, Zenhausern is not found deficient.

***Conclusion***

11. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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